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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,007	01/18/2006	Anne-Marie Pintel	34930158PUS1	7203
2292 7590 06/19/2007 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			EXAMINER AUDET, MAURY A	
			ART UNIT	PAPER NUMBER
			1654	
			NOTIFICATION DATE	DELIVERY MODE
			06/19/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/565,007

Applicant(s)

PINEL ET AL.

Examiner

Maury Audet

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17, 19 and 23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-17, 19, 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>03/06, 03/06, 01/06</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The present application has been transferred from former Examiner Young to the present Examiner.

Election/Restrictions

Applicant's election with traverse of Group II, claims 12-14, 16, and 17, in the reply filed on 3/26/07 is acknowledged. The traversal is on the ground(s) that the prior art cited no longer teaches the invention, at least part, based on the amended claims. This Examiner agrees based on the negative limitation provided ("not coupled with zinc"), and the traversal is thus deemed moot (although the original restriction groups are maintained for the reasons of record). This Examiner is willing to rejoin claims 15 and 19 as well.

The requirement is still deemed proper and is therefore made FINAL. Claims 12-17, 19, and new claim 23 are pending and examined on the merits.

Claim Rejections - 35 USC § 112 1st Written Description

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-17, 19, and 23 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a "written description" rejection, rather than an enablement rejection under 35 U.S.C. 112, first paragraph. Applicant is directed to the

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Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Vas-Cath Inc. V. Mahurka, 19 USPQ2d 1111, states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention, for purposes of the "written description" inquiry, is *whatever is now claimed*" (see page 1117).

The claimed invention is drawn to the use of a peptide conjugate formula of core tripeptide Gly-His-Lys (and specifically SEQ ID NOS: 5-14) for the treatment of alopecia and hair loss, including any form of enantiomers, diastereoisomers, mixtures thereof, including racemix mixtures of said peptide conjugate.

One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the claimed genus of any form of enantiomers, diastereoisomers, mixtures thereof, including racemix mixtures of said peptide conjugate. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (see *Vas-Cath* at page 1116). Namely, although the specification describes peptide conjugates containing the tripeptide Gly-His-Lys, no enantiomers, diastereoisomers, mixtures thereof, including racemix mixtures were found to be described.

Thus, neither the claims nor the specification adequately describe the claimed genus of any enantiomers, diastereoisomers, mixtures thereof, including racemix mixtures, comprising the tripeptide conjugate comprising Gly-His-Lys. With the substantial variability among the broad genus, contemplating any such variants of the above peptide conjugates, it is not recognizable

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what the structure of these variants would be? One of skill in the art would not recognize from the disclosure that the Applicant was in possession of the genus, namely any form of enantiomers, diastereoisomers, mixtures thereof, including racemix mixtures of said peptide conjugate comprising the tripeptide conjugate comprising Gly-His-Lys.

Claim Rejections - 35 U.S.C. § 112 1st Scope

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-17, 19, and 23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for “treating” an individual who has alopecia or hair loss with a tripeptide conjugate comprising Gly-His-Lys **AND** a compound known to improve hair regrowth (e.g. claim 17 compounds), does not reasonably provide enablement for any of:

1. *preventing or cur[ing]* (curative) alopecia or hair loss with Gly-His-Lys tripeptide conjugates;
2. *preventing or cur[ing]* (curative) alopecia or hair loss Gly-His-Lys tripeptide conjugates **AND** a compound known to improve hair regrowth (e.g. claim 17 compounds); **OR**
3. treating alopecia or hair loss simply by applying a peptide conjugate comprising the tripeptide Gly-His-Lys.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these

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claims.

Applicants have reasonably demonstrated/disclosed that the claimed Gly-His-Lys peptides, combined with a compound known to improve hair regrowth (e.g. claim 17 compounds) will "treat" alopecia or hair loss. However, the claims also encompass using the claimed composition to prevent/cure the above, which is clearly beyond the scope of the instantly disclosed/claimed invention. Please note that the term "prevent"/"cure" is an absolute definition which means to stop from occurring and, thus, requires a higher standard for enablement than does the term "treat", especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot be totally prevented/cured with current therapies (other than certain vaccination regimes) - including preventing/curing such disorders as alopecia/hair loss (which clearly is not recognized in the medical art as being a totally preventable condition).

Accordingly, it would take undue experimentation without a reasonable expectation of success for one of skill in the art to make and/or use the claimed composition which would function to prevent/cure alopecia/hair loss using Gly-His-Lys tripeptide conjugates alone or Gly-His-Lys tripeptide conjugates AND a compound known to improve hair regrowth (e.g. claim 17 compounds).

Additionally, Applicant has provided no evidence either via the specification or recitation of prior art (and none found to the same, unless used with Zinc) that merely administering tripeptide conjugates comprising Gly-His-Lys will prevent/cure or treat alopecia/hair loss. Thus, the latter is not enabled either, absent the addition (e.g. claim 17, which is not in independent claim 12) of known compounds that improve (e.g. treat) alopecia or hair loss.

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Applicant may wish to consider amending “a compound known to improve hair regrowth (e.g. claim 17 compounds)” into the base claim.

Claim Rejections - 35 USC § 112 2nd

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12-17, 19, and 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 12, it is unclear what is meant by “effective amount”? The description of how much of the conjugate comprising the tripeptide Gly-His-Lys must be administered to increase hair growth and treat alopecia and hair loss was not clearly identified.

MPEP 2173.05(c)

III. “EFFECTIVE AMOUNT”

The common phrase “an effective amount” may or may not be indefinite. The proper test is whether or not one skilled in the art could determine specific values for the amount based on the disclosure. See *In re Mattison*, 509 F.2d 563, 184 USPQ 484 (CCPA 1975). The phrase “an effective amount . . . for growth stimulation” was held to be definite where the amount was not critical and those skilled in the art would be able to determine from the written disclosure, including the examples, what an effective amount is. *In re Halleck*, 422 F.2d 911, 164 USPQ 647 (CCPA 1970). The phrase “an effective amount” has been held to be indefinite when the claim fails to state the function which is to be achieved and more than one effect can be implied from the specification or the relevant art. *In re Fredericksen* 213 F.2d 547, 102 USPQ 35 (CCPA 1954). The more recent cases have tended to accept a limitation such as “an effective amount” as being definite when read in light of the supporting disclosure and in the absence of any prior art which would give rise to uncertainty about the scope of the claim. In *Ex parte Skuballa*, 12 USPQ2d 1570 (Bd. Pat. App. & Inter. 1989), the Board held that a pharmaceutical composition claim which recited an “effective amount of a compound of claim 1” without stating the function to be achieved was definite, particularly when read in light of the supporting disclosure which provided guidelines as to the intended utilities and how the

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uses could be effected.

In claim 12, in the line beginning "X represents ... , or a bond,"; it is unclear what the invention is? Namely, whether a single, two, or three Lys residues may be optionally conjugated between the Gly residue and "A" OR a bond and no Lys residue(s) at all. Or whether "a bond" is an option off one of the Lys residues (left open), rather than being methylated?

Additionally claim 12 is unclear because X cannot represent "a chain of 1 to 3 Lys residues" if only one Lys residue is attached. One Lys residue cannot be a chain.

Claims 17, line 1 and 19, line 4, are indefinite because the phrase "combined with/to". It is unclear whether these additional agents are to be conjugated to the tripeptide Gly-His-Lys conjugate or added to *a composition* comprising the tripeptide Gly-His-Lys conjugate. If the former, Applicant must provide evidence where (as not found in the specification). If the latter, the base claim 12 must be amended to a "composition comprising a conjugate" rather than merely a conjugate used in the method.

Claim Observations

In claim 12, where appropriate, semi-colons would be helpful to maintain the distinction between the different variables.

In claim 19, line 3, it is suggested that the term "or" be deleted and the mnemonic "PABA" be put in parenthesis after its full name.

In claims 13-17, and 19, after the phrase "chosen from", it is suggested that the phrase "the group consisting of" be put in proper Markush format.

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Conclusion

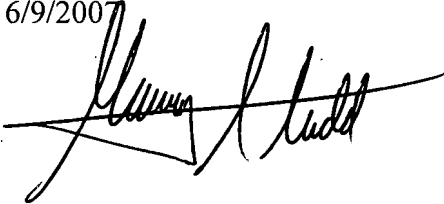
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 6/9/2007

A handwritten signature in black ink, appearing to read 'Maury Audet', written over a horizontal line.

MAURY AUDET
PATENT EXAMINER